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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,902	01/25/2001	Reba Goodman	61545/JPW/RAD	5006

7590 10/20/2004
John P. White
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New York, NY 10036

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,902

Applicant(s)

GOODMAN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,13,22 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,22 and 30 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 September 2004 has been entered.

Claims 1-30 were under consideration in the Final Office Action mailed 19 May 2004. Claims 2-7, 9-12, 14-21 and 23-29 were canceled and claims 1, 13 and 22 were amended in the 22 September Paper. Claims 1, 8, 13, 22 and 30 are pending and under consideration.

Response to Amendment

Rejection of claims 2-7, 9-12, 14-21 and 23-29 is rendered moot by the cancellation thereof.

Claim Rejections - 35 USC § 112

Claims 1, 8, 22 and 30 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record and herein below in the response to arguments.

Rejection of claims 13 under 35 U.S.C. § 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn.

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Rejection of claims 1, 8, 13, 22 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 112

In response to the *prima facie* case and arguments of record regarding the failure of the disclosure to enable the claimed method for *in vivo* application, Applicant has amended claim 1 such that the method is no longer limited to being practiced in the context of a gene therapy and has amended the claims such that the gene promoter is limited to comprising a 900 base pair segment of the c-myc promoter fused to a HSP70 gene promoter heat shock responsive element. Applicant asserts, based on these amendments, that the claims are now limited to the enabled scope.

As stated in the 29 December Office Action and reiterated in the 19 May Office Action, “Claims 22-30 are directed to a method for regulating expression of a nucleic acid in a cell using the electromagnetic field responsive promoter. According to the broadest reasonable interpretation, the claims encompass a method of regulating expression *in vitro* or *in vivo*. As the specification provides no asserted utility or guidance as to how the skilled artisan is to use the method *in vivo* other than gene therapy, the claims lack enablement for the method practiced *in vivo* for the reasons set forth in previous Office Actions” (bridging pages 7-8). The amendments to the claims and Applicant’s remarks do not address these grounds for rejection. Claims 1, 8, 22 and 30 still embrace a method for regulating the expression of an exogenous gene *in vivo*, for

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which the application fails to provide an enabled use. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claims.

New Grounds

Claim Objections

Claims 1, 13 and 22 are objected to because of the following informalities: Claim 1, part (a), the second line of claim 13 and the fifth line of claim 22 each recite the phrase “segment of c-myc promoter”. According to proper English grammar, there should be an article between “of” and “c-myc”. It is recommended that the phrase be amended to recite, “segment of a c-myc promoter”. Appropriate correction is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "D. Sullivan", with a long horizontal flourish extending to the right.

Daniel M Sullivan, Ph.D.
Examiner
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